DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

August15, 2014

Kaltenbach & Voigt GmbH
Mr. Stefan Trampler
Head of Quality Management & Regulatory Affairs
Bismarckring 39
Biberach, Germany, 88400

Re: K140308
Trade/Device Name: MASTERsurg/EXPERTsurg
Regulation Number: 21 CFR 872.4200
Regulation Name: Dental Handpieces and Accessories
Regulatory Class: I
Product Code: EBW, EGS
Dated: May 15, 2014
Received: May 19, 2014

Dear Mr. Trampler:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mary S. Runner -
S

Erin I. Keith, M.S
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section IV - Indications for Use

K140308

510(k) Number (if known): K140308

Device Name: ***MASTERsurg / EXPERTsurg***

Indications for Use:

EXPERTsurg:

This KaVo product is intended for surgery to expose and dissect oral tissue structures or endodontic treatments (e.g. periodontal gap, gingiva, bone, jaw, extractions and implantations).

INTRA LUX S600 LED:

The medical device is intended to drive / operate a dental handpiece / contra-angle handpiece equipped with a handpiece connection according to ISO 3964. This medical device is an electrical low-voltage motor for dental purposes according to ISO 11498 type 2 and classified as a type B application part.

SURGmatic S201 L / C; SURGmatic S201 XL / XC; SURGmatic S11 L / C:

The medical device is intended for the following uses: Surgery such as setting an implant, bone augmentation, sinus lift, tooth extraction procedures, implantology, osteotomia, root resection and oral, jaw and facial surgery.

Prescription Use ___X____ (Part 21 CFR 801 Subpart D)

AND / OR

Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

KaVo. Dental Excellence.

Section V - 510(k) Summary

Submitter:

Kaltenbach & Voigt GmbH
Bismarckring 39
88400 Biberach
Stefan Trampler - Contact Person
49 (7351) 56 3515 - Phone number
+49 (7351) 56 7 3515 - Facsimile

Date Summary Prepared: May, 14th 2014

Device Name:

- Trade Name - ***MASTERsurg / EXPERTsurg***
- Common Name - Controller, Foot, Handpieces and Cord (EBW)
  - Handpiece, Contra-Angle Attachment, Dental (EGS)
- Classification Name - Dental handpiece and accessories, per 21 CFR § 872.4200

Devices for Which Substantial Equivalence is Claimed:

- CHIROPRO L SYSTEM (K092214) marketed by Bien-Air Dental SA
- SURGICAL STRAIGHT & CONTRA-ANGEL HANDPIECES (K011061) marketed from W & H DENTALWERK BUERMOOS GMBH

Device Description:

The ***MASTERsurg / EXPERTsurg*** is a dental surgical system out of:

- EXPERTsurg (surgical control unit)
- INTRA LUX S600 LED (surgical motor)
- SURGmatic S201 L / C (handpieces)
- SURGmatic S201 XL / XC (handpieces)
- SURGmatic S11 L / C (handpieces)

The ***MASTERsurg / EXPERTsurg*** is a system out of a surgical control unit (***EXPERTsurg***), a surgical motor (***INTRA LUX S600 LED***) and different handpieces (***SURGmatic***).

The surgical control unit (***EXPERTsurg***) consists of a surgical controller, a foot controller, a motor cable, an instruments tray, a holder and a tube set. The surgical motor (***INTRA LUX S600 LED***) consists of the motor, a stopper for maintenance purposes and exchange O-rings for the motor coupling.

As a functional principle the software-based surgical control unit controls the speed and torque of a dental micro motor. The unit is equipped with a pump for the use with external irrigation tubing allowing irrigation of the working area. The surgical control unit is operated through the buttons on the tabletop console or via foot control. The surgical control unit is intended to be used with the INTRA LUX S600 LED motor. Straight or contra-angle handpieces with a handpiece connection according to ISO 3964 can be equipped. The instrument tray allows the dentist to deposit the ***SURGmatic*** *handpieces* in a safe position. The holder is intended to be used for general storage. The tube set is needed to deliver the external irrigation from the bottle (not part of this 510(k)) to the ***SURGmatic*** *handpieces*. A power cord provides electric power to the unit. The ***EXPERTsurg*** will be delivered with software on the surgical control unit. The ***EXPERTsurg*** follows the international standards for electrical safety and electromagnetic compatibility which are applicable for the use with human beings.

Each of the different handpieces (***SURGmatic***) consists of the handpiece, a spray clip (only SURGmatic S201 L / C and SURGmatic S201 XL / XC), a jet needle for cleaning purposes and a tube for the external spray.

The ***SURGmatic*** handpieces are electrical driven dental handpieces for the use by a trained professional in the field of general dentistry. The devices are electrical-powered handpieces that are reusable and ergonomically shaped, and provided with a fiber optic light system (L version). The devices can be sterilized by the steam autoclave method. Through the INTRA LUX S600 LED motor connected to the surgical control unit, the ***SURGmatic*** handpieces equipped with a handpiece connection according to ISO 3964 receives the energy, the cooling water and air for treatment and the light for illumination the operation area (L version). Surgical burs and cutters (with straight handpiece shank or with contra-angle shank) according to ISO 1797 can be used with the ***SURGmatic*** handpieces. The ***SURGmatic*** handpieces use external spray allowing external irrigation to the working area. The mechanism of action for the ***SURGmatic*** handpieces is as follows. The dental straight and contra-angle handpieces are electrical-driven handpieces which will be supplied with energy, air and light through the dental micro motor of the surgical control unit. Dental burs (not part of this 510(k)) according to ISO 1797 could be inserted into the chuck system of the handpieces. Based on the speed adjusted in the surgical control unit the handpiece bur rotates up to 40,000 rpm. The ***SURGmatic*** handpieces interacts with the patient through a rotating bur with the patient teeth according to the intended use.

Intended Use of the Device:

EXPERTsurg:

This KaVo product is intended for surgery to expose and dissect oral tissue structures or endodontic treatments (e.g. periodontal gap, gingiva, bone, jaw, extractions and implantations).

INTRA LUX S600 LED:

The medical device is intended to drive / operate a dental handpiece / contra-angle handpiece equipped with a handpiece connection according to ISO 3964. This medical device is an electrical low-voltage motor for dental purposes according to ISO 11498 type 2 and classified as a type B application part.

SURGmatic S201 L / C; SURGmatic S201 XL / XC; SURGmatic S11 L / C:

The medical device is intended for the following uses: Surgery such as setting an implant, bone augmentation, sinus lift, tooth extraction procedures, implantology, osteotomia, root resection and oral, jaw and facial surgery.

Substantial Equivalence:

The ***MASTERsurg / EXPERTsurg*** dental surgical system out of a surgical control unit (***EXPERTsurg***), a surgical motor (***INTRA LUX S600 LED***) and different handpieces (***SURGmatic***) is substantially equivalent to other legally marketed devices in the United States. The ***MASTERsurg / EXPERTsurg*** functions in a manner similar to and is intended for the same use as the CHIROPRO L SYSTEM (K092214) marketed by Bien-Air Dental SA and to the SURGICAL STRAIGHT & CONTRA-ANGEL HANDPIECES (K011061) marketed by W & H DENTALWERK BUERMOOS GMBH.

The ***EXPERTsurg*** surgical control unit together with the surgical motor (***INTRA LUX S600 LED***) is similar to the predicate device CHIROPRO L SYSTEM (K092214) from Bien-Air Dental SA in that it is a software-based surgical control unit which controls the speed and torque of a dental micro motor as the functional principle. As the CHIROPRO L SYSTEM (K092214) from Bien-Air Dental SA the ***EXPERTsurg*** surgical control unit together with the surgical motor (***INTRA LUX S600 LED***) consists of a surgical control unit, a foot controller, a surgical motor, an instruments tray, a holder and a tube set. The ***EXPERTsurg*** surgical control unit together with the surgical motor (***INTRA LUX S600 LED***) and the CHIROPRO L SYSTEM (K092214) from Bien-Air Dental SA are equipped with a pump for the use with external irrigation tubing allowing irrigation of the working area. The surgical control units are operated through the buttons on the tabletop console or via foot control. Both units are intended to be used with a dental micro motor equipped with straight or contra-angle handpieces with a handpiece connection according to ISO 3964 can be equipped. The CHIROPRO L SYSTEM (K092214) from Bien-Air Dental SA as well as the ***EXPERTsurg*** surgical control unit together with the surgical motor (***INTRA LUX S600 LED***) will be delivered with software and the devices follow the international standards for electrical safety and electromagnetic compatibility which are applicable for the use with human beings.

The ***SURGmatic (S201 L/C, S201 XL/XC and S11 L/C)*** handpieces are similar to the predicate devices SURGICAL STRAIGHT & CONTRA-ANGEL HANDPIECES (K011061) from W & H DENTALWERK BUERMOOS GMBH in that the dental straight and contra-angle handpieces are electrical-driven handpieces which will be supplied with energy, air and light through a dental micro motor of a surgical control unit as the mechanism of action. As the SURGICAL STRAIGHT & CONTRA-ANGEL HANDPIECES (K011061) from W & H DENTALWERK BUERMOOS GMBH the ***SURGmatic*** handpieces are reusable (The devices can be sterilized by the steam autoclave method) handpieces provided with a fiber optic light system (where applicable). Surgical burs and cutters (with straight handpiece shank or with contra-angle shank) according to ISO 1797 can be used for both, the ***SURGmatic*** handpieces and the SURGICAL STRAIGHT & CONTRA-ANGEL HANDPIECES (K011061) from W & H DENTALWERK BUERMOOS GMBH. In addition both handpiece types, the ***SURGmatic*** handpieces and the SURGICAL STRAIGHT & CONTRA-ANGEL HANDPIECES (K011061) from W & H DENTALWERK BUERMOOS GMBH use external spray allowing external irrigation to the working area.

The ***EXPERTsurg*** surgical control unit together with the surgical motor (***INTRA LUX S600 LED***) differ from the CHIROPRO L SYSTEM (K092214) marketed by Bien-Air Dental SA in a few technical characteristics (f.e. protection class, dimensions, flow rate of the pump, Motor Torque and weight).

The ***SURGmatic (S201 L/C, S11 L/C and S201 XL/XC)*** handpieces differ from the SURGICAL STRAIGHT & CONTRA-ANGEL HANDPIECES (K011061) marketed by W & H DENTALWERK BUERMOOS GMBH in a few technical characteristics (f.e. dimensions, light intensity and lubrication). The maximum speed of the SURGICAL STRAIGHT & CONTRA-ANGEL HANDPIECES (K011061) marketed by W & H DENTALWERK BUERMOOS GMBH is 50,000 rpm in difference to 40,000 rpm of the ***SURGmatic*** handpieces.

The differences do not render the device NSE because the performance tests demonstrates that the differences in technological characteristics do not raise different questions of safety and effectiveness than the predicate and show that the device is as safe and effective as the predicate.

Summary of the Technological Characteristics:

Descriptive Information	Surgical control unit (EXPERTsurg) and Surgical motor (INTRA LUX S600 LED)	
	EXPERTsurg + INTRA LUX S600 LED	**Chiropro L System (K092214)** (Bien-Air Dental SA)
Indications for Use	Unit: This KaVo product is intended for surgery to expose and dissect oral tissue structures or endodontic treatments (e.g. periodontal gap, gingiva, bone, jaw, extractions and implantations). Motor: The medical device is intended to drive / operate a dental handpiece / contra-angle handpiece equipped with a handpiece connection according to ISO 3964. This medical device is an electrical low-voltage motor for dental purposes according to ISO 11498 type 2 and classified as a type B application part.	The Chiropro L System is intended for use in dental surgery, endodontics and implantology. The main unit is designed to operate a specific dental micro motor that drives dental handpieces fitted with appropriate tools to cut hard and soft tissues in the mouth and to screw dental implants.
Device Components	Surgical control unit with tubing + motor	Identical
Compliance to Standards	Electrical low voltage motor for dental purposes according to ISO 11498 type 2	Identical
Functional Principle	This surgical unit consists of a software-based drive unit that controls the speed and torque of a dental micro motor. The unit is equipped with a pump for the use with external irrigation tubing allowing irrigation of the working area. The device is operated through the buttons on the tabletop console or via foot control. The system (unit and micro motor) is intended to be used with contra-angle handpieces or straight instruments.	Identical
Insulation class	II	Identical
Protection class	IP20	IP40
Dimensions	265 x 255 x 100 mm	242 x 241 x 137 mm
Flow Rate (Pump)	30 - 110 ml / min.	30 - 125 ml / min.
Electrical Specification Device (Voltage)	100 - 240 V	Identical
Electrical Specification Device (Power)	230 VA	Unknown
Motor Type	Surgical Motor (collector)	Identical
Handpiece Connection	INTRAmatic Coupling System (ISO 3964)	Identical
Electrical Specification Motor (Voltage)	22 V AC	Unknown
Electrical Specification Motor (Torque)	5,5 Ncm	6,8 Ncm
Electrical Specification Motor (Rotation)	Clockwise, Counter Clockwise	Identical
Electrical Specification Motor (Speed)	Up to 40,000 rpm	Identical
Electrical Specification Motor (Light)	With built-in light system (LED)	Identical
Motor Weight	125 g	119 g
Intended Users	Dentists	Identical

Descriptive Information	Dental Handpieces (SURGmatic)	
	SURGmatic S201 L / C SURGmatic S201 XL / XC SURGmatic S11 L / C	**Surgical Straight & Contra-angle Handpieces (K011061)** (W & H DENTALWERK BUERMOOS GMBH)
Indications for Use	The medical device is intended for the following uses: Surgery such as setting an implant, bone augmentation, sinus lift, tooth extraction procedures, implantology, osteotomia, root resection and oral, jaw and facial surgery.	This medical device is intended for indications in the field of implantology and surgery (f.e. osteotomia on the upper and lower jaw, germectomia, sequestrotomia, implantology, hemisection, wisdom tooth extraction, root tip resection, bone removal, surgical modellation, apical ventilation. Fenestration, bone modellation)
Functional Principle	Through the micro motor connected to the surgical unit the straight and contra-angle handpieces / instruments equipped with a handpiece connection according to ISO 3964 receives the energy, the cooling water and air for treatment and the light for illumination the operating area.	Identical
Air / water ports	External Spray	Identical
Fiberoptics	With and Without built-in light system	Identical
Dimensions (with motor)	Headsize-Height: Up to 13,7 mm Headsize-Diameter: Up to 9,8 mm Front diameter: Up to 7,3 mm	Unknown
Type of chuck	Push Button, lever chuck	Identical
Rotary Instruments	For Surgical Burs and Cutters (with straight handpiece shank or with contra-angle shank) according to ISO 1797	Identical
Dimensions	Approx. 80 - 100 mm	Identical
Speed Range	Up to 40,000 rpm	Up to 50,000 rpm
Chemical composition of the patient-contacting portions of the device	(See details in Section XV)	Unknown
Chemical composition of the water / air lines	(See details in Section XV)	Unknown
Light Intensity	Approx. 25,000 LUX	Daylight
Bur retention force	Up to 22 Ncm (45 Ncm)	Identical
Compliance to Standards	Complies with ISO 14457, ISO 1797, ISO 3964	Identical
Lubricant	KaVo QUATTROcare (K071288)	Unknown (Own Lubricant from W&H)
Sterilization	Sterilizable (See details in Section XIV)	Identical

Non-Clinical Test Data:

Temperature and energy tests according to the international standards for electrical safety and electromagnetic compatibility have been conducted to determine the conformance to the state of the art. Biocompatibility studies have been completed which demonstrate that the ***MASTERsurg / EXPERTsurg*** is safe for his intended use.

Additionally, the ***MASTERsurg / EXPERTsurg*** software has been successfully validated to confirm the performance of the device.

Clinical Test Data:

Clinical testing has not been conducted on this product.

Conclusion:

Based upon the tests according to the international standards for electrical safety and electromagnetic compatibility, the biocompatibility studies, the similar technological / performance characteristics as compared to the predicate devices, and successful validation of the ***MASTERsurg / EXPERTsurg*** software, the performance of the ***MASTERsurg / EXPERTsurg*** is deemed to be substantially equivalent to the predicate devices.